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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :  
KEI KIRIBAYASHI, ET AL. : EXAMINER: HENRY, M.C.  
SERIAL NO: 10/533,538 :  
FILED: MAY 2, 2005 : GROUP ART UNIT: 1623  
FOR: PERITONEAL DIALYSIS :  
METHOD

APPEAL BRIEF

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

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(i) Real Party in Interest

Kowa Co., Ltd. is the real party in interest.

(ii) Related Appeals or Interferences

The Appellants are unaware of any related appeals or interferences that would directly affect, be directly affected by, or have a bearing on the Board's decision in this appeal.

(iii) Status of the Claims

Claims 11-36 are on Appeal. Claims 11, 18, 19, 21 and 33 are independent claims on Appeal.

No claims stand withdrawn from consideration as being directed to a non-elected invention.

Claims 1-10 have been cancelled.

The Claims Appendix below provides a clean copy of the claims on appeal entered by the Amendment filed January 6, 2010.

(iv) Status of the Amendment

The Amendment filed on January 6, 2010 has been entered.

(v) Summary of the Claimed Subject Matter

The invention is directed to a peritoneal dialysis method that is less damaging to subjects undergoing repeated or long-term peritoneal dialysis procedures. The Appellants have discovered that injuries to the peritoneum caused by repeated administration of a conventional peritoneal dialysate can be prevented by administering a dialysate containing *adenosine triphosphate (ATP)*, see the first paragraph on page 1 of the specification.

Peritoneal dialysate solutions are used for patients in advanced stages of renal failure who cannot sufficiently remove body wastes, specification, page 1, lines 11 *ff.* A peritoneal dialysis solution containing a high concentration of glucose is introduced into the peritoneum for a period of 5-6 hours to osmotically adsorb body wastes and is subsequently removed (along with the absorbed wastes), specification, page 2, lines 15-19. However since patients are treated with peritoneal dialysis over a long period of time this process can cause hardening of the peritoneum or peritonitis due to repeated exposure to a high concentration of glucose contained in the peritoneal dialysate, specification, page 2, lines 9 *ff.* The inventors discovered that use of a peritoneal dialysate containing adenosine triphosphate (ATP) reduces peritoneal injuries, see the paragraph bridging pages 2-3 of the specification.

Support for the claims is indicated in brackets below:

11. A peritoneal dialysis method for treating a peritoneal injury [**claim 18, page 4, line 5**] or for treating a cell injury caused by sugar [**claim 20, page 4, line 8**] comprising:

administering to a patient having a peritoneal injury or a cell injury caused by sugar a dialysate comprising adenosine triphosphate or a salt thereof [**claims 11-20, page 3, lines 4-5**].

12. The peritoneal dialysis method of claim 11, wherein said patient is suffering from a renal disease, and said dialysate is administered intraperitoneally via a catheter implanted in the peritoneal cavity [**see original claim 12**].

13. The peritoneal dialysis method of claim 11 or 12, wherein the concentration of adenosine triphosphate or a salt thereof in the dialysate ranges from 10 to 5,000  $\mu\text{M}$  [**see original claim 13**].

14. The peritoneal dialysis method of claim 11 or 12, wherein the dialysate further comprises glucose and an electrolyte [**see original claim 14**].

15. The peritoneal dialysis method of claim 14, wherein the glucose level ranges from 1,000 to 4,000 mg/dL [**see original claim 15**].

16. The peritoneal dialysis method of claim 11, further comprising:  
administering a dialysate containing a high level of glucose into a patient suffering a renal disease through a catheter implanted in the peritoneal cavity after administering said dialysate containing adenosine triphosphate or a salt thereof and a physiological level of glucose [**see original claim 16**].

17. The peritoneal dialysis method of claim 16, wherein the physiological glucose level ranges from 0.08 to 0.16% (w/v) and the high glucose level ranges from 1,000 to 4,000 mg/dL **[see original claim 17]**.

18. A treating method for peritoneal injury, characterized by administering an effective amount of adenosine triphosphate or a salt thereof to a subject in need thereof **[see original claim 18]**.

19. A treating method for cell injury caused by sugar, characterized by administering an effective amount of adenosine triphosphate or a salt thereof to a subject in need thereof **[see original claim 19]**.

20. The method as described in claim 19, wherein the cell injury caused by sugar is peritoneal mesothelial cell injury caused by glucose **[see original claim 20]**.

21. A peritoneal dialysis method for treating a peritoneal injury or for treating a cell injury caused by sugar, comprising:

administering into the peritoneal cavity of a subject having a peritoneal injury or a cell injury caused by sugar an effective amount of a composition comprising adenosine triphosphate or a salt thereof **[see original claims 11, 18 and 20; page 4, line 8]**.

22. The method of claim 21, wherein said composition further comprises glucose and electrolytes **[see original claim 14]**.

23. The method of claim 21, wherein said composition contains:

10 to 5,000  $\mu\text{M}$  of adenosine triphosphate or a salt thereof [**claim 13**],

1,000 to 4,000 mg/dL glucose [**claim 17**],

100 to 200 mEq/L  $\text{Na}^+$  [**page 6, line 11**],

4 to 5 mEq/L  $\text{Ca}^{2+}$  [**page 6, line 12**],

1 to 2 mEq/L  $\text{Mg}^{2+}$  [**page 6, line 12**], and

80 to 120 mEq/L  $\text{Cl}^-$  [**page 6, line 13**].

24. The method of claim 23, wherein said composition also contains 30 to 50 mEq/L of an organic acid [**page 6, line 15**].

25. The method of claim 23, wherein said composition also contains 30 to 50 mEq/L of lactic acid [**page 6, line 15**].

26. The method of claim 21, wherein said composition has an osmotic pressure ranging between 300 and 700 mOsm/L [**page 6, line 17**].

27. The method of claim 21, wherein said subject has renal failure [**page 1, line 11**].

28. The method of claim 21, wherein said subject has peritoneal mesothelial cell injuries caused by exposure to high levels of sugar [**page 3, line 3**].

29. (Previously Presented): The method of claim 21, wherein said subject has hardening of the peritoneum or peritonitis **[page 2, line 12]**.

30. The method of claim 21, wherein said subject has sclerotic encysted peritonitis or intractable prolonged peritonitis **[page 6, last paragraph]**.

31. The method of claim 18, comprising administering a solution containing:

adenosine triphosphate or a salt thereof **[claims 11 and 18]**,  
1,000 to 4,000 mg/dL glucose **[claim 15]**, and  
electrolytes **[page 6]**.

32. The method of claim 19, comprising administering a solution containing:

adenosine triphosphate or a salt thereof **[claims 11 and 18]**,  
1,000 to 4,000 mg/dL glucose **[claim 15]**, and  
electrolytes **[page 6]**.

33. A peritoneal dialysis method comprising:  
administering to a patient in need of dialysis a dialysate comprising  
adenosine triphosphate or a salt thereof **[claims 11 and 18]**.

34. The peritoneal dialysis method of claim 33 comprising administering  
a peritoneal dialysate comprising a conventional peritoneal dialysis solution that

does not contain adenosine triphosphate and adenosine triphosphate [**claims 11 and 18; pages 1-2**].

35. The peritoneal dialysis method of claim 33, wherein the dialysate contains 10 to 5,000  $\mu\text{M}$  of adenosine triphosphate [**claim 13**].

36. The peritoneal dialysis method of claim 33, wherein said patient has hardening of the peritoneum or peritonitis or other damage to the peritoneum characterized by mesothelial cell injury caused by prior exposure to a peritoneal dialysis solution that does not contain adenosine triphosphate [**claims 11 and 18; page 2, first full paragraph**].

(vi) Grounds of Rejection to be Reviewed on Appeal

A. Whether Claims 11-36 are unpatentable under 35 U.S.C. §103(a) as being obvious over Isono, et al., U.S. Patent No. 5,871,477.

B. Whether Claim 34 is indefinite under 35 U.S.C. §112, second paragraph

(vii) Argument(s)

Issue A: Rejection under 35 U.S.C. §103

Claims 11-36 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Isono, et al., U.S. Patent No. 5,871,477. The main issue in this case is simple: the Examiner has misinterpreted the disclosure of Isono, et al., which is focused describing **medical containers**, as disclosing (i) a method for treating subjects having peritoneal injury using (ii) a peritoneal dialysate containing adenosine triphosphate (ATP). The Examiner is wrong on both points since Isono does not disclose subjects having peritoneal injury, nor does it disclose a peritoneal dialysate containing ATP.

Isono is totally silent about treating subjects having **peritoneal injury** even though it discloses conventional dialysis solutions not containing ATP.

Isono is also totally silent about peritoneal dialysate solution or methods of peritoneal dialysis using a dialysis solution **containing ATP**. Isono does disclose and exemplifies an organ-preservation solution that optionally may contain ATP but is silent about administering organ-preservation solutions to dialysis patients having peritoneal injuries. As discussed below, no responsible medical practitioner would administer an organ-preservation solution to a dialysis patient.

The obviousness rejection is based on the Examiner's misinterpretation of the prior art teachings in col. 2, lines 5-47 of Isono which he continues to assert disclose or suggest a peritoneal dialysate containing adenosine triphosphate (ATP). On page 3, lines 14-16, the Examiner states:

Furthermore, **Isono et al. disclose or suggest that adenosine triphosphate solution which is an organ-preserving solution can be added to said peritoneal dialysate** (see col. 2, lines 5-46, especially lines 34-46).

Only the paragraph at col. 2, lines 5-21 of Isono describes a peritoneal dialysate. Two separate paragraphs spanning col. 2, lines 22-47, including lines 34-46 relied upon by the rejection, describe organ-preserving solutions and components of organ-preserving solutions like ATP that may be added to an organ-preserving solution. These last two paragraphs relied upon by the Examiner have nothing to do with peritoneal dialysates. As clearly exemplified by Isono in col. 2, peritoneal dialysates and organ-preserving solutions contain different ingredients, for example, a peritoneal dialysate contains high concentrations of glucose not present in the organ-preserving solution described by Isono and lacks the heparin found in organ preserving solution exemplified by Isono. The paragraphs in col. 2, lines 22-47 of Isono describe ingredients commonly found in organ-preserving solutions including anticoagulants like heparin. ATP is disclosed at col. 2, line 41 as one possible ingredient of an organ-preserving solution. ATP is simply not disclosed as an ingredient of a peritoneal dialysate. There is no support for the Examiner's assertion that Isono discloses or suggests that adenosine triphosphate solution "can be added to said peritoneal dialysate". Moreover, Isono does not confuse these different types of electrolyte solutions and no one skilled in the medical arts would have confused them.

Isono is primarily directed to a medical container containing an electrolyte solution and is not directed to formulating new types of electrolyte solutions. In conjunction with disclosure of the container, Isono incidentally describes different types of electrolyte solutions that the medical container might hold such as "a body fluid replenisher", "a dialysate" and "an electrolyte solution", it does not disclose a peritoneal dialysate solution containing ATP, does not provide any motivation for adding ATP to a peritoneal dialysate, and consequently, cannot

provide a reasonable expectation for the superior properties of a peritoneal dialysate containing ATP.

These facts have been pointed out to the Examiner and Office several times, most recently in the Pre-Appeal Brief, yet the Examiner persistently maintains that Isono, col. 2, lines 5 to 46 discloses or suggests a *peritoneal dialysate* that contains ATP, not recognizing that ATP mentioned in col. 2 is only described as an ingredient for an organ-preservation solution and that Isono fails to provide any motivation for adding ATP to a peritoneal dialysis solution or any reasonable expectation of success for reducing injury to patients undergoing peritoneal dialysis by doing so.

Since Isono does not disclose a peritoneal dialysate containing ATP either in col. 2 or elsewhere, provide any motivation for adding ATP to a peritoneal dialysate, or provide a reasonable expectation of success for reducing peritoneal injury by adding ATP to a peritoneal dialysate, this rejection cannot be sustained.

The Appellants present their arguments in more detail below.

Isono, et al. does not disclose or suggest all the elements of the invention:

- (1) a peritoneal dialysis solution containing adenosine triphosphate, or
- (2) the step of administering a peritoneal dialysis solution containing adenosine triphosphate to a patient.

Isono also does not provide:

- (3) a reasonable expectation of success that administering a peritoneal dialysis solution containing ATP would ameliorate damage caused by hyperosmotic sugar concentration in conventional peritoneal dialysis solutions to the mesothelial cells which line the peritoneum.

With respect to point (1) above, as discussed in the Appellants prior responses, Isono does not disclose a peritoneal dialysis solution. Those of ordinary skill in the art understand that peritoneal dialysis solutions have particular osmotic and compositional characteristics that permit them to function in methods of dialysis. These include hyperosmotic properties conferred by the relatively high sugar concentrations needed to perform peritoneal dialysis.

On the other hand, while Isono describes conventional dialysis solutions that do not contain ATP (see col. 2, lines 5-33) and depicts conventional methods of dialysis in Fig. 13, it does not disclose or suggest adding ATP to a dialysis solution.

Rather, Isono discloses “organ-preserving solutions” that may optionally include “adenosine triphosphate” or optionally contain numerous other types of drugs and compounds useful for organ preservation, see the list in col. 2, lines 35-47. Moreover, the exemplary organ-preservation solution of Isono (col. 2, lines 26-34) contains heparin--an ingredient missing from the exemplary peritoneal dialysis solution in col. 2, lines 9-17--and unlike the conventional dialysis solution is devoid of a glucose (or indeed any hyperosmotic concentration of sugar).

The Office’s conflation of a *dialysis* solution with an *organ-preservation* solution is improper and cannot support a *prima facie* basis for an obviousness rejection. While the final Official Action (“OA”) explicitly states that “Isono et al.’s composition does not contain adenosine triphosphate” (OA, bottom of page 3), it contends that such a dialysis solution is suggested by Isono.

However, Isono clearly distinguishes amongst the different physiological solutions that may be contained within the medical container it discloses.

Namely, cols. 1 and 2 of Isono distinguish between (i) infusion solutions, (ii) dialysate, and (iii) an organ (tissue) preserving solution, see col. 1, lines 21-24, and col. 1, lines 51-col. 2, line 4 describing infusion solutions, col. 2, lines 5-21 which disclose dialysates, and col. 2, lines 35-47 which describe organ-preserving solutions. It is evident from these portions of the reference that Isono recognized the significant compositional differences between a peritoneal dialysis solution and different types of solutions used to preserve organs.

Based on these distinctions and the level of ordinary skill in the medical arts, one would not have used an organ preservation solution to perform peritoneal dialysis even if it contained ATP. This clearly would not be accepted by those of ordinary skill in the art and would, in fact, subject any medical practitioner using an organ-preservation solution for peritoneal dialysis (or *vice versa* using a dialysis solution to preserve an organ) to serious claims of medical malpractice.

With regard to point (2) above, since col. 2 of Isono does not suggest a peritoneal dialysis solution containing adenosine triphosphate, it also cannot suggest the claimed method of performing peritoneal dialysis with a solution containing ATP. Isono suggests that ATP might be one ingredient useful in an “organ preservation” solution, but does not suggest and fails to recognize the value of ATP in a peritoneal dialysis solution. Assuming *arguendo*, that Isono did suggest a peritoneal dialysis solution containing adenosine triphosphate (ATP), which it does not, it provided no suggestion select such a dialysate for the treatment of peritoneal injury or cell injury caused by sugar.

Page 4, lines 7-9 of the OA state that:

One of ordinary skill in the art would have been motivated in view of Isono et al., to treat peritoneal injury or a cell injury in a subject

by administering a composition comprising a combination of adenosine triphosphate, glucose, and electrolytes as a peritoneal dialysate.

However, the Examiner has not pointed out any support in Isono for this alleged motivation for treating peritoneal injury or for administering a dialysis solution containing ATP. As noted above, Isono only describes adenosine triphosphate (ATP) in the context of one of many potential additives for an organ-preserving solution, not for use as in a peritoneal dialysis solution. The Examiner has not pointed out any other portion of Isono suggesting administering “a dialysate comprising adenosine triphosphate” to a patient having a peritoneal injury or cell injury caused by sugar” as required by independent claim 11.

Furthermore, adenosine triphosphate is not recognized as a conventional component of dialysis solution as evident from the citations below:

(1) Wikipedia (last modified on 2 January 2010 at 18:56);

[http://en.wikipedia.org/wiki/Peritoneal\\_dialysis](http://en.wikipedia.org/wiki/Peritoneal_dialysis); see evidence appendix):

**Peritoneal dialysis** (PD) is a treatment for patients with severe chronic kidney failure. The process uses the patient's peritoneum in the abdomen as a membrane across which fluids and dissolved substances (electrolytes, urea, glucose, albumin and other small molecules) are exchanged from the blood. Fluid is introduced through a permanent tube in the abdomen and flushed out either every night while the patient sleeps (automatic peritoneal dialysis) or via regular exchanges throughout the day (continuous ambulatory peritoneal dialysis). PD is used as an alternative to hemodialysis though it is far less common. It has comparable risks and expenses, with the primary advantage being the ability to undertake treatment without visiting a medical facility. The primary complication with PD is a risk of infection due to the presence of a permanent tube in the abdomen.

(ii) Package insert from Baxter U.S. describing components of a peritoneal dialysis solution:

[http://www.baxter.com/products/renal/peritoneal\\_dialysis/sub/solutions.html](http://www.baxter.com/products/renal/peritoneal_dialysis/sub/solutions.html) (last accessed August 5, 2009; see evidence appendix).

(iii) Technical literature from Baxter Healthcare Corporation (attached).

Even if, for the sake of argument, Isono disclosed a peritoneal dialysis solution containing one of the ingredients used to prepare organ-preservation solutions, such as adenosine triphosphate, it did not suggest treatment of the subclasses of patients required by the invention using such a composition or that selection of ATP would provide any benefit. For example, there is no suggestion at all in Isono for the subclasses of subjects of claims 28, 29 and 36.

Furthermore, with regard to point (3) above, Isono cannot provide a reasonable expectation of success for the invention which as shown by the experimental data of record reduces peritoneal injury caused by glucose by incorporating ATP. For example, Fig. 1 shows that inclusion of adenosine triphosphate alleviates the decreased viability of peritoneal mesothelial cells caused by increasing sugar concentrations; see also the top of page 10 of the specification. Fig. 2 shows that substitution of adenosine for adenosine triphosphate (ATP) did not alleviate the decrease in peritoneal mesothelial cell viability. This indicates the importance of the selection of ATP. Figs. 3-5 show that the viability increasing effect of ATP is inhibited by adenosine triphosphate antagonists, again showing the importance of selecting ATP. Isono does not provide a reasonable expectation that inclusion of adenosine triphosphate (ATP) in a dialysate would provide this superior effect.

This rejection is improper because Isono does not (i) teach all the elements of the invention, namely a peritoneal dialysate solution containing adenosine triphosphate and the step of administering such an ATP-containing solution to a

patient in need of peritoneal dialysis, (ii) does not suggest using a dialysate containing adenosine triphosphate to ameliorate peritoneal damage or cell injury caused by sugar, and (iii) does not provide a reasonable expectation of success for treating a peritoneal injury caused by sugar using such a method. Therefore, taking into account all of these reasons, as well as the experimental and technical data of record, this rejection cannot be sustained.

Issue B: Rejection—35 U.S.C. §112, second paragraph

Claim 34 was rejected under 35 U.S.C. 112, second paragraph, as indefinite for use of the phrase “a conventional peritoneal dialysis solution that does not contain adenosine triphosphate and adenosine triphosphate”. This phrase simply refers to a composition containing two components (i) a conventional peritoneal dialysis solution that does not contain adenosine triphosphate” and (ii) adenosine triphosphate which together provide “a peritoneal dialysate containing ATP” as disclosed on page 3, lines 11-12 of the specification. Page 9, 2<sup>nd</sup> paragraph, of the specification also discloses admixture of a conventional dialysate with adenosine triphosphate. Moreover, the art applied by the Examiner establishes that conventional peritoneal dialysate solutions not containing adenosine triphosphate were well-known in the art, see Isono, U.S. Patent No. 5,871,477, col. 2, lines 10-16. Therefore, this phrase when read in light of the specification and prior art would have been clear to one of skill in the art at the time of invention. Consequently, this rejection cannot be sustained.

The arguments above apply at least in equal force to each pending claim. The dependent claims all contain further limitations that establish their patentability apart from those in the independent claims. These limitations include the particular concentrations of ingredients required by claims 13, 15, 17, 23-26, 31, 32 and 35, which have not been addressed by the rejection, as well as the particular disorders described by claims 20, 21, 27-30 and 36 which have not been established in the prior art. For all of the reasons above, this rejection cannot be sustained.

RELIEF REQUESTED

The Appellants respectfully request REVERSAL of the grounds of rejection above and the allowance of this application.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

A handwritten signature in black ink, appearing to read "Thomas Cunningham". The signature is written in a cursive, flowing style.

Customer Number  
**22850**

Thomas M. Cunningham  
Registration No.: 45,394

(viii) Claims Appendix

1 -10. (Cancelled)

11. A peritoneal dialysis method for treating a peritoneal injury or for treating a cell injury caused by sugar comprising:

administering to a patient having a peritoneal injury or a cell injury caused by sugar a dialysate comprising adenosine triphosphate or a salt thereof.

12. The peritoneal dialysis method of claim 11,  
wherein said patient is suffering from a renal disease, and  
said dialysate is administered intraperitoneally via a catheter implanted in the peritoneal cavity.

13. The peritoneal dialysis method of claim 11 or 12, wherein the concentration of adenosine triphosphate or a salt thereof in the dialysate ranges from 10 to 5,000  $\mu\text{M}$ .

14. The peritoneal dialysis method of claim 11 or 12, wherein the dialysate further comprises glucose and an electrolyte.

15. The peritoneal dialysis method of claim 14, wherein the glucose level ranges from 1,000 to 4,000 mg/dL.

16. The peritoneal dialysis method of claim 11, further comprising:

administering a dialysate containing a high level of glucose into a patient suffering a renal disease through a catheter implanted in the peritoneal cavity after administering said dialysate containing adenosine triphosphate or a salt thereof and a physiological level of glucose.

17. The peritoneal dialysis method of claim 16, wherein the physiological glucose level ranges from 0.08 to 0.16% (w/v) and the high glucose level ranges from 1,000 to 4,000 mg/dL.

18. A treating method for peritoneal injury, characterized by administering an effective amount of adenosine triphosphate or a salt thereof to a subject in need thereof.

19. A treating method for cell injury caused by sugar, characterized by administering an effective amount of adenosine triphosphate or a salt thereof to a subject in need thereof.

20. The method as described in claim 19, wherein the cell injury caused by sugar is peritoneal mesothelial cell injury caused by glucose.

21. A peritoneal dialysis method for treating a peritoneal injury or for treating a cell injury caused by sugar, comprising:

administering into the peritoneal cavity of a subject having a peritoneal injury or a cell injury caused by sugar an effective amount of a composition comprising adenosine triphosphate or a salt thereof.

22. The method of claim 21, wherein said composition further comprises glucose and electrolytes.

23. The method of claim 21, wherein said composition contains:

10 to 5,000  $\mu\text{M}$  of adenosine triphosphate or a salt thereof,

1,000 to 4,000 mg/dL glucose,

100 to 200 mEq/L  $\text{Na}^+$ ,

4 to 5 mEq/L  $\text{Ca}^{2+}$ ,

1 to 2 mEq/L  $\text{Mg}^{2+}$ , and

80 to 120 mEq/L  $\text{Cl}^-$ .

24. The method of claim 23, wherein said composition also contains 30 to 50 mEq/L of an organic acid.

25. The method of claim 23, wherein said composition also contains 30 to 50 mEq/L of lactic acid.

26. The method of claim 21, wherein said composition has an osmotic pressure ranging between 300 and 700 mOsm/L.

27. The method of claim 21, wherein said subject has renal failure.

28. The method of claim 21, wherein said subject has peritoneal mesothelial cell injuries caused by exposure to high levels of sugar.

29. (Previously Presented): The method of claim 21, wherein said subject has hardening of the peritoneum or peritonitis.

30. The method of claim 21, wherein said subject has sclerotic encysted peritonitis or intractable prolonged peritonitis.

31. The method of claim 18, comprising administering a solution containing:

adenosine triphosphate or a salt thereof,  
1,000 to 4,000 mg/dL glucose, and  
electrolytes.

32. The method of claim 19, comprising administering a solution containing:

adenosine triphosphate or a salt thereof,  
1,000 to 4,000 mg/dL glucose, and  
electrolytes.

33. A peritoneal dialysis method comprising:

administering to a patient in need of dialysis a dialysate comprising  
adenosine triphosphate or a salt thereof.

34. The peritoneal dialysis method of claim 33 comprising administering a peritoneal dialysate comprising a conventional peritoneal dialysis solution that does not contain adenosine triphosphate and adenosine triphosphate.

35. The peritoneal dialysis method of claim 33, wherein the dialysate contains 10 to 5,000  $\mu\text{M}$  of adenosine triphosphate.

36. The peritoneal dialysis method of claim 33, wherein said patient has hardening of the peritoneum or peritonitis or other damage to the peritoneum characterized by mesothelial cell injury caused by prior exposure to a peritoneal dialysis solution that does not contain adenosine triphosphate.

(ix) Evidence Appendix

1. Wikipedia Entry: [http://en.wikipedia.org/wiki/Peritoneal\\_dialysis](http://en.wikipedia.org/wiki/Peritoneal_dialysis)

(last modified on 2 January 2010 at 18:56).

2. Package insert.

[http://www.baxter.com/products/renal/peritoneal\\_dialysis/sub/solutions.ht](http://www.baxter.com/products/renal/peritoneal_dialysis/sub/solutions.ht)

ml

(last accessed August 5, 2009).

(x) Related Proceedings Appendix

(None)